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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/416,022 | 10/08/99 | AGOURIDAS | 146,1327 |

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BIERMAN MUSERLIAN AND LUCAS
600 THIRD AVENUE
NEW YORK NY 10016

EXAMINER
COLEMAN, B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1624 | |

DATE MAILED: 06/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/416,022

Applicant(s)
AGOURIDAS et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 2, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-13 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-12 is/are rejected.
- 7) ☒ Claim(s) 6 and 13 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Claims 1-4 and 6-13 are pending in the application.

This action is in response to applicant's amendment filed April 2, 2001. Claims 1, 7 and 10-12 have been amended and claim 5 has been canceled.

Response to Amendment

Applicant's arguments filed April 2, 2001 have been fully considered with the following effect:

1. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejections labeled a) and c)-f). However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled b) and g) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

- b) The applicants' stated that "claim 7 has been amended to insert the appropriate parenthesis". However, the nomenclature of the second species still contains an unmatched closed parenthesis following 18-hydroxymethyl.

Claims 7, 9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- g) The applicants' stated that "reference has been inserted to refer to a compound of formula I which therefor provides antecedent basis for R and B". However, the

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definition of B in claim 12 is different than the definition of B in claim 1 with respect to formula I.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

2. With regards to the 35 U.S.C. § 102, anticipation rejections of claims 1-5 and 7-11 by Phan et al., U.S. Patent Number 6,124,269 and WO 99/21871 of the last office action, the applicant's amendments and arguments have been fully considered but are not found persuasive. The applicants' stated that the "amended claims no longer read upon the compounds wherein R is hydrogen". However, the first species of claim 7 is where R, R₁, R₂ and Z are H; A is nitrogen; and Hal is fluorine which is taught by example 1 of Phan.

Claims 7, 9 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Phan et al., WO 99/21871. Phan teaches the compounds, compositions and method of use of the instant invention where A is nitrogen; R, R₁ and R₂ are hydrogen; Hal is F; and Z is hydrogen. See example 1. For reasons of record and stated above.

Claims 7, 9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Phan et al., U.S. 6,124,269. Phan teaches the compounds, compositions and method of use of the instant invention where A is nitrogen; R, R₁ and R₂ are hydrogen; Hal is F; and Z is hydrogen. See example 1. For reasons of record and stated above.

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3. The applicant's amendments are sufficient to overcome the 35 USC § 103, obviousness rejection of claims 1-5 and 7-11 in the last office action, which is hereby **withdrawn**.

In view of the amendment dated April 2, 2001, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1-4, 8 and 10 are vague and indefinite in that it is not known what is meant by the moiety $C(=O)-Ar_2OB-(CH_2)_n-Ar$ in the definition of B. The variable B in the definition of B creates a continuous loop for which there is no final definition of B. It is believed that the definition of B in claim 1 includes the moieties in claim 12 where B is $-C(=O)-Ar$ or $-(CH_2)_n-Ar$.
- b) Claims 7, 9 and 11 are vague and indefinite in that the nomenclature of the first species contains several typographical errors, i.e. [3-aS-(3aR*, 4S*, 7R*, 9S*, 11S*, 13S*, 15S*, 15aS*)]-4-ethyl-7-fluoro-3a, 4, 10, 11, 12, 13, 15, 15a-octahydro-11-methoxy-3a, 7, 9, 11, 13, 15-hexamethyl-10-[[3,4,6-trideoxy-3-(dimethyl-amino)-

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.beta.-D-xylo-hexopyranosyll]oxy]-14,1-(nitriloethano)-2H-

oxacyclotetradecino[4,3-]oxazole-2,6,8(9H)-trione. It is believed that this species is example 1 where the following items appear:

- 1) a hyphen appears between 3-aS;
 - 2) 10S* is missing between 9S* and 11S*;
 - 3) dimethylamino is separated by a hyphen;
 - 4) hexopyranosyll ends with two l's; and
 - 5) the ring fusion is missing the d, i.e. [4,3-d].
- c) Claims 7, 9 and 11 are vague and indefinite in that the nomenclature of the second species contains several typographical errors, i.e. [3aS-(3aR*, 4S*, 7R*, 9S*, 10S*, 11S*, 13A*, 15S*, 15aS*, 17R*)]-4-ethyl-7-fluoro-3a, 4, 10, 11, 12, 13, 15, 15a-octahydro-18-hydroxymethyl)-11-methoxy-3a, 7, 9, 11, 13, 15-hexamethyl-10-[[3-4,6-trideoxy-3-(dimethylamino)-.beta.-D-xylohexopyranosyl]oxy]-14,1-(nitriloethano)-2H-oxacyclotetradecino[4,3-d]oxazole-2,6,8(9H)-trione. It is believed that this species is example 2 where the following items appear:
- 1) 3aR* appears but is not present in example 2 on pages 14-15;
 - 2) 4S* is 4R in example 2;
 - 3) 7R* is 7S in example 2;
 - 4) 9S* is 9R in example 2;
 - 5) 10S* is 10R in example 2;

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- 6) 11S* is 11R in example 2;
 - 7) 13A* is 13R in example 2;
 - 8) 15S* is 15R in example 2;
 - 9) 15aS* is 15aR in example 2;
 - 10) 17R* is 18S in example 2;
 - 11) a hyphen appears between 3 and 4 in 3-4,6-trideoxy;
 - 12) there is a hyphen missing between xylo and hexopyranosyl; and
 - 13) 7H is missing, i.e. (7H,9H).
- d) Claims 7, 9 and 11 recite the limitation "hydrogen" in the species for the variable R. There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

4. Claims 6 and 13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. None of the prior art of record nor a search in the pertinent art area teaches the substitution of the diazepine ring or the intermediates as claimed herein.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Monday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brenda Coleman
June 12, 2001